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Orchid Healthcare,  
Orchid Chemicals & Pharmaceuticals Ltd. and  
Organus Pharma Inc.*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

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SEPRACOR INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC.,  
TEVA PHARMACEUTICAL INDUSTRIES,  
LTD., WOCKHARDT LTD., WOCKHARDT  
USA, INC., DR. REDDY'S LABORATORIES,  
LTD., DR. REDDY'S LABORATORIES,  
INC., ROXANE LABORATORIES, INC.,  
COBALT LABORATORIES INC., COBALT  
PHARMACEUTICALS INC., GLENMARK  
GENERICs INC., USA, GLENMARK  
GENERICs, LTD., GLENMARK  
PHARMACEUTICALS, LTD., ORCHID  
HEALTHCARE (a Division of ORCHID  
CHEMICALS & PHARMACEUTICALS,

Civil Action No. 2:09-CV-01302

Hon. Dennis M. Cavanaugh, U.S.D.J.  
Hon. Mark Falk, U.S.M.J.

**Document Electronically Filed**

LTD.), ORCHID CHEMICALS & PHARMACEUTICALS, LTD., ORGENUS PHARMA INC., LUPIN PHARMACEUTICALS, INC., LUPIN LTD., SUN PHARMA GLOBAL INC., SUN PHARMACEUTICAL INDUSTRIES INC., SUN PHARMACEUTICAL INDUSTRIES LTD., ALPHAPHARM PTY. LTD. and MYLAN, INC.,

Defendants.

**ANSWER, DEFENSES AND COUNTERCLAIMS**

Defendants Orchid Healthcare (a Division of Orchid Chemicals & Pharmaceuticals Ltd.), Orchid Chemicals & Pharmaceuticals Ltd. (“Orchid Ltd.”) and Orgenus Pharma Inc. (“Orgenus”) (collectively, “Orchid”), hereby answer the complaint of Plaintiff Sepracor Inc. (“Sepracor”), for which every allegation not expressly admitted is denied, as follows:

**PARTIES**

1.A. Plaintiff Sepracor is a Delaware corporation having its principal place of business at 84 Waterford Drive, Marlborough, MA 01752.

**ANSWER:** Orchid lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1.A., and therefore denies all such allegations.

1.B. – 1.R.

**ANSWER:** Paragraphs 1.B.-1.R. contain allegations directed toward Defendants other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

1.S. Upon information and belief, Defendant Orchid Healthcare is an unincorporated division of Defendant Orchid Ltd., having a place of business at Plot No. B3-B6 & B11-B14, Sipcot Industrial Park, Irungattukottai, Sriperumbudur (TK) - 602 105, Kancheepuram District, Tamil Nadu, India. Upon information and belief, Defendant Orchid Healthcare, itself and through Defendants Orchid Ltd. and Orgenus, markets and sells generic drugs throughout the

United States, including in this judicial district. Upon information and belief, Defendant Orchid Healthcare has previously admitted personal jurisdiction in this Court.

**ANSWER:** Paragraph 1.S. contains legal conclusions to which no answer is required. To the extent an answer is required, Orchid admits that Orchid Healthcare is an operating division of Orchid Ltd., which has a place of business at Plot Nos. B3 – B6 & B11 – B14, SIPCOT Industrial Park, Irungattukottai—602 105, Sriperumbudur, Kancheepuram District, India, and that Orchid Ltd. manufactures quality generic drug products. To conserve the resources of the parties and the Court, and for purposes of judicial efficiency, Orchid Healthcare does not contest personal jurisdiction for purposes of this action only. Orchid denies the remaining allegations of this Paragraph.

1.T. Upon information and belief, Defendant Orchid Ltd. is an Indian corporation having a place of business at Orchid Towers, #313, Valluvar Kottam High Road, Nungambakkam, Chennai - 600 034, Tamil Nadu, India. Upon information and belief, Defendant Orchid Ltd., itself and through its wholly owned subsidiary and agent Defendant Orgenus, manufactures generic drugs for sale and use throughout the United States, including in this judicial district. Upon information and belief, Defendant Orchid Ltd. is registered to do business in New Jersey and does business in this judicial district. Defendant Orchid Ltd. has previously admitted personal jurisdiction in this Court.

**ANSWER:** Paragraph 1.T. contains legal conclusions to which no answer is required. To the extent an answer is required, Orchid admits that Defendant Orchid Ltd. is an Indian corporation having a place of business at Orchid Towers, #313, Valluvar Kottam High Road, Nungambakkam, Chennai - 600 034, Tamil Nadu, India, and that Orchid Ltd. manufactures quality generic drug products. To conserve the resources of the parties and the Court, and for purposes of judicial efficiency, Orchid Ltd. does not contest personal jurisdiction for purposes of this action only. Orchid denies the remaining allegations of this Paragraph.

1.U. Upon information and belief, Defendant Orgenus is a New Jersey corporation having a place of business at 700 Alexander Park, Suite 104, Princeton, New Jersey 08540. Upon information and belief, Defendant Orgenus is a wholly owned subsidiary and agent of Defendant Orchid Ltd. Upon information and belief, Orgenus is registered to do business in

New Jersey and does business in this judicial district. Defendant Orgenus has previously admitted personal jurisdiction in this Court.

**ANSWER:** Paragraph 1.U. contains legal conclusions to which no answer is required. To the extent an answer is required, Orchid admits that Orgenus is a New Jersey Corporation having a place of business at 700 Alexander Park, Suite 104, Princeton, NJ 08450. To conserve the resources of the parties and the Court, and for purposes of judicial efficiency, Orgenus does not contest personal jurisdiction for purposes of this action only. Orchid denies that Orgenus is a proper party to this suit. Orchid denies the remaining allegations of this Paragraph.

1.V. Defendant Orchid Healthcare, Defendant Orchid Ltd., and Defendant Orgenus are collectively referred to as "Orchid."

**ANSWER:** Admitted.

1.W. - 1.FF.

**ANSWER:** Paragraphs 1.W.-1.FF. contain allegations directed toward Defendants other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

#### **NATURE OF THE ACTION**

2. This is a civil action for the infringement of United States Patent No. 6,864,257 ("the '257 patent"), United States Patent No. 6,319,926 ("the '926 patent"), United States Patent No. 6,444,673 ("the '673 patent") and United States Patent No. 7,381,724 ("the '724 patent"). This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*

**ANSWER:** Paragraph 2 contains legal conclusions to which no answer is required. To the extent that an answer is required, Orchid admits that Plaintiffs' Complaint purports to assert a claim arising under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*, for alleged infringement of United States Patent No. 6,864,257 ("the '257 patent"), United States Patent No. 6,319,926 ("the '926 patent"), United States Patent No. 6,444,673 ("the '673

patent") and United States Patent No. 7,381,724 ("the '724 patent"). Orchid denies the remaining allegations of this Paragraph.

**JURISDICTION AND VENUE**

3. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court as to each Defendant pursuant to 28 U.S.C. §§ 1391(b), (c) and/or (d) and 1400(b).

**ANSWER:** Paragraph 3 contains legal conclusions to which no answer is required. To the extent an answer by Orchid is required, Orchid admits that subject matter jurisdiction is proper for the claims asserted against Orchid Healthcare and Orchid Ltd. under 35 U.S.C. § 271(e)(2)(A) only. Orchid denies that there is subject matter jurisdiction for any claims asserted against Orgenus, or for any claims asserted against any Defendant under 35 U.S.C. §§ 271(a), (b) or (c). Further answering, to conserve the resources of the parties and the Court, and for the purposes of judicial efficiency, Orchid does not contest venue in this judicial district for purposes of this action only. Orchid denies the remaining allegations of this Paragraph.

4. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, aided, abetted, contributed to and/or participated in the commission of a tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiff Sepracor. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth above and below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

**ANSWER:** Paragraph 4 contains legal conclusions to which no answer is required. To the extent an answer by Orchid is required, denied. Further answering, to conserve the resources of the parties and the Court, and for purposes of judicial efficiency, Orchid does not contest personal jurisdiction for purposes of this action only. Orchid denies the remaining allegations of this Paragraph.

5. - 16.

**ANSWER:** Paragraphs 5-16 contain allegations directed toward Defendants other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

17. This Court has personal jurisdiction over Defendant Orchid Healthcare.

**ANSWER:** Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer is required, to conserve the resources of the parties and the Court, and for purposes of judicial efficiency, Orchid Healthcare does not contest personal jurisdiction for purposes of this action only. Orchid denies the remaining allegations of this Paragraph.

18. This Court has personal jurisdiction over Defendant Orchid Ltd.

**ANSWER:** Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer is required, to conserve the resources of the parties and the Court, and for purposes of judicial efficiency, Orchid Ltd. does not contest personal jurisdiction for purposes of this action only. Orchid denies the remaining allegations of this Paragraph.

19. This Court has personal jurisdiction over Defendant Orgenus.

**ANSWER:** Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is required, to conserve the resources of the parties and the Court, and for purposes of judicial efficiency, Orgenus does not contest personal jurisdiction for purposes of this action only. Orchid denies the remaining allegations of this Paragraph. Orchid further denies that Orgenus is a proper party to this suit.

20. - 26.

**ANSWER:** Paragraphs 20-26 contain allegations directed toward Defendants other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

### **THE PATENTS**

27. On March 8, 2005, the '257 patent, titled "Optically Active 5H-Pyrrolo[3,4-B] Pyrazine Derivative, Its Preparation and Pharmaceutical Compositions Containing It," was duly and legally issued to Sepracor as assignee. Since that time, Sepracor has been, and continues to be, the sole owner of the '257 patent and the sole owner of the right to sue and to recover for any infringement of that patent. A copy of the '257 patent is attached hereto as Exhibit A.

**ANSWER:** Paragraph 27 contains legal conclusions to which no answer is required. To the extent an answer is required, Orchid admits that, according to the electronic records of the United States Patent and Trademark Office ("PTO"), on or about March 8, 2005, the PTO issued the '257 patent, entitled "Optically Active 5H-pyrrolo[3,4-b]pyrazine Derivative, Its Preparation And Pharmaceutical Compositions Containing It," to Claude Cotrel and Gérard Roussel; that the face of the '257 patent identifies "Sepracor Inc." as the "assignee;" and that what purports to be a copy of the '257 patent is attached to the Complaint as Exhibit A. Orchid expressly denies that the '257 patent was "duly and legally issued." Orchid denies the remaining allegations of this Paragraph.

28. On September 3, 2002, the '673 patent, titled "Optically Active 5H-Pyrrolo[3,4-B] Pyrazine Derivative, Its Preparation and Pharmaceutical Compositions Containing It," was duly and legally issued to Sepracor as assignee. Since that time, Sepracor has been, and continues to be, the sole owner of the '673 patent and the sole owner of the right to sue and to recover for any infringement of that patent. A copy of the '673 patent is attached hereto as Exhibit B.

**ANSWER:** Paragraph 28 contains legal conclusions to which no answer is required. To the extent an answer is required, Orchid admits that, according to the electronic records of the PTO, on or about September 3, 2002, the PTO issued the '673 patent, entitled

“Optically Active 5H-pyrrolo[3,4-b]pyrazine Derivative, Its Preparation And Pharmaceutical Compositions Containing It,” to Claude Cotrel and Gérard Roussel; that the electronic records of the PTO identify “Sepracor Inc.” as the “assignee” of the ‘673 patent; and that what purports to be a copy of the ‘673 patent is attached to the Complaint as Exhibit B. Orchid expressly denies that the ‘673 patent was “duly and legally issued.” Orchid denies the remaining allegations of this Paragraph.

29. On November 20, 2001, the ’926 patent, titled “Optically Active 5H-Pyrrolo[3,4-B] Pyrazine Derivative, Its Preparation and Pharmaceutical Compositions Containing It,” was duly and legally issued to Sepracor as assignee. Since that time, Sepracor has been, and continues to be, the sole owner of the ’926 patent and the sole owner of the right to sue and to recover for any infringement of that patent. A copy of the ’926 patent is attached hereto as Exhibit C.

**ANSWER:** Paragraph 29 contains legal conclusions to which no answer is required. To the extent an answer is required, Orchid admits that, according to the electronic records of the PTO, on or about November 20, 2001, the PTO issued the ’926 patent, entitled “Optically Active 5H-pyrrolo[3,4-b]pyrazine Derivative, Its Preparation And Pharmaceutical Compositions Containing It,” to Claude Cotrel and Gérard Roussel; that the electronic records of the PTO identify “Sepracor Inc.” as the “assignee” of the ‘926 patent; and that what purports to be a copy of the ‘926 patent is attached to the Complaint as Exhibit C. Orchid expressly denies that the ‘926 patent was “duly and legally issued.” Orchid denies the remaining allegations of this Paragraph.

30. On June 3, 2008, the ’724 patent, titled “Optically Active 5H-Pyrrolo[3,4-B] Pyrazine Derivative, Its Preparation and Pharmaceutical Compositions Containing Same,” was duly and legally issued to Sepracor as assignee. Since that time, Sepracor has been, and continues to be, the sole owner of the ’724 patent and the sole owner of the right to sue and to recover for any infringement of that patent. A copy of the ’724 patent is attached hereto as Exhibit D.

**ANSWER:** Paragraph 30 contains legal conclusions to which no answer is required. To the extent an answer is required, Orchid admits that, according to the electronic

records of the PTO, on or about June 3, 2008, the PTO issued the ‘724 patent, entitled “Optically Active 5H-pyrrolo[3,4-b]pyrazine Derivative, Its Preparation And Pharmaceutical Compositions Containing Same,” to Claude Cotrel and Gérard Roussel; that the face of the ‘724 patent identifies “Sepracor Inc.” as the “assignee;” and that what purports to be a copy of the ‘724 patent is attached to the Complaint as Exhibit D. Orchid expressly denies that the ‘724 patent was “duly and legally issued.” Orchid denies the remaining allegations of this Paragraph.

**ACTS GIVING RISE TO THIS ACTION**

**INFRINGEMENT OF THE ‘257 PATENT**

**COUNT I – INFRINGEMENT OF THE ‘257 PATENT BY TEVA**

31. Plaintiff realleges paragraphs 1-30 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-30, as if fully set forth herein.

32. – 39.

**ANSWER:** Paragraphs 32-39 contain allegations directed toward a Defendant other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

**COUNT II – INFRINGEMENT OF THE ‘257 PATENT BY REDDY**

40. Plaintiff realleges paragraphs 1-39 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-39, as if fully set forth herein.

41. – 48.

**ANSWER:** Paragraphs 41-48 contain allegations directed toward a Defendant other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

**COUNT III – INFRINGEMENT OF THE ‘257 PATENT BY ROXANE**

49. Plaintiff realleges paragraphs 1-48 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-48, as if fully set forth herein.

50. – 56.

**ANSWER:** Paragraphs 50-56 contain allegations directed toward a Defendant other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

**COUNT IV – INFRINGEMENT OF THE ‘257 PATENT BY COBALT**

57. Plaintiff realleges paragraphs 1-56 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-56, as if fully set forth herein.

58. – 65.

**ANSWER:** Paragraphs 58-65 contain allegations directed toward a Defendant other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

**COUNT V – INFRINGEMENT OF THE ‘257 PATENT BY GLENMARK**

66. Plaintiff realleges paragraphs 1-65 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-65, as if fully set forth herein.

67. – 74.

**ANSWER:** Paragraphs 67-74 contain allegations directed toward a Defendant other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

## COUNT VI – INFRINGEMENT OF THE '257 PATENT BY ORCHID

75. Plaintiff realleges paragraphs 1-74 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-74, as if fully set forth herein.

76. Upon information and belief, Defendant Orchid submitted ANDA No. 91-113 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 91-113 seeks the FDA approval necessary to engage in the commercial manufacture, use and sale of generic tablets containing 1 mg, 2 mg or 3 mg of the active ingredient eszopiclone prior to the expiration of the '257 patent. ANDA No. 91-113 specifically seeks FDA approval to market a proposed generic version of Sepracor's Lunesta® brand 1 mg, 2 mg and 3 mg eszopiclone tablets prior to the expiration of the '257 patent.

**ANSWER:** Paragraph 76 contains legal conclusions to which no answer is required. To the extent an answer is required, Orchid admits that Orchid Healthcare (an operating division of Orchid Ltd.) submitted an Abbreviated New Drug Application ("ANDA") to the FDA seeking approval for Eszopiclone Tablets, 1 mg, 2 mg and 3 mg, before the expiration of the '257 patent. Orchid denies that Orgenus submitted such an ANDA. Orchid denies all remaining allegations of this Paragraph.

77. ANDA No. 91-113 alleges under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '257 patent are either invalid or not infringed by the manufacture, use or sale of the proposed generic versions of Sepracor's Lunesta® brand products. Sepracor received written notification of ANDA No. 91-113 and the § 505(j)(2)(A)(vii)(IV) allegations on February 20, 2009.

**ANSWER:** Paragraph 77 contains legal conclusions to which no answer is required. To the extent an answer is required, Orchid admits that Orchid Healthcare's ANDA contains a so-called "Paragraph IV Certification," stating that the '257 patent is invalid, unenforceable and/or will not be infringed, either directly or indirectly, by the manufacture, sale or use of the drug products for which Orchid Healthcare submitted its ANDA. Orchid further admits, on information and belief, that Sepracor received the required notice of Orchid

Healthcare's ANDA on or about February 20, 2009. Orchid denies all remaining allegations of this Paragraph.

78. Orchid's submission to the FDA of ANDA No. 91-113, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '257 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

79. Orchid Healthcare, Orchid Ltd. and Orgenus are jointly and severally liable for any infringement of the '257 patent. This is because, upon information and belief, Orchid Healthcare, Orchid Ltd. and Orgenus actively and knowingly caused to be submitted, assisted with, participated in, contributed to and/or directed the submission of ANDA No. 91-113 and the § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

**ANSWER:** Denied.

80. Orchid's active and knowing participation in, contribution to, aiding, abetting and/or inducement of the submission to the FDA of ANDA No. 91-113 and the § 505(j)(2)(A)(vii)(IV) allegations constitutes infringement of the '257 patent under 35 U.S.C. § 271(e)(2)(A). Orchid's commercial manufacture, use, offer for sale, importation or sale of its proposed generic versions of Sepracor's Lunesta® brand products, or inducement of or contribution to such conduct, would further infringe the '257 patent under 35 U.S.C. § 271(a), (b) and/or (c).

**ANSWER:** Denied.

81. Upon information and belief, Orchid was aware of the existence of the '257 patent and was aware that filing of the ANDA and certification with respect to the '257 patent constituted an act of infringement of that patent.

**ANSWER:** Paragraph 81 contains legal conclusions to which no answer is required. To the extent an answer is required, Orchid admits that Orchid Healthcare was aware of the '257 patent when Orchid Healthcare submitted its ANDA. Orchid denies all remaining allegations of this Paragraph.

82. This case is an exceptional one and Sepracor is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**ANSWER:** Denied.

83. Sepracor will be irreparably harmed by Orchid's infringing activities unless those activities are enjoined by this Court. Sepracor does not have an adequate remedy at law.

**ANSWER:** Denied.

**COUNT VII – INFRINGEMENT OF THE '257 PATENT BY LUPIN**

84. Plaintiff realleges paragraphs 1-83 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-83, as if fully set forth herein.

85. – 92.

**ANSWER:** Paragraphs 85-92 contain allegations directed toward a Defendant other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

**COUNT VIII – INFRINGEMENT OF THE '257 PATENT BY SUN**

93. Plaintiff realleges paragraphs 1-92 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-92, as if fully set forth herein.

94. – 101.

**ANSWER:** Paragraphs 94-101 contain allegations directed toward a Defendant other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

**COUNT IX – INFRINGEMENT OF THE '257 PATENT BY ALPHAPHARM**

102. Plaintiff realleges paragraphs 1-101 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-101, as if fully set forth herein.

103. – 110.

**ANSWER:** Paragraphs 103-110 contain allegations directed toward a Defendant other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

**INFRINGEMENT OF THE '673 PATENT**

**COUNT X – INFRINGEMENT OF THE '673 PATENT BY WOCKHARDT**

111. Plaintiff realleges paragraphs 1-110 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-110, as if fully set forth herein.

112. – 119.

**ANSWER:** Paragraphs 112-119 contain allegations directed toward a Defendant other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

**COUNT XI – INFRINGEMENT OF THE '673 PATENT BY REDDY**

120. Plaintiff realleges paragraphs 1-119 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-119, as if fully set forth herein.

121. – 128.

**ANSWER:** Paragraphs 121-128 contain allegations directed toward a Defendant other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

**COUNT XII – INFRINGEMENT OF THE '673 PATENT BY ROXANE**

129. Plaintiff realleges paragraphs 1-128 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-128, as if fully set forth herein.

130. – 136.

**ANSWER:** Paragraphs 130-136 contain allegations directed toward a Defendant other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

**COUNT XIII – INFRINGEMENT OF THE '673 PATENT BY COBALT**

137. Plaintiff realleges paragraphs 1-136 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-136, as if fully set forth herein.

138. – 145.

**ANSWER:** Paragraphs 138-145 contain allegations directed toward a Defendant other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

**COUNT XIV – INFRINGEMENT OF THE '673 PATENT BY GLENMARK**

146. Plaintiff realleges paragraphs 1-145 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-145, as if fully set forth herein.

147. – 154.

**ANSWER:** Paragraphs 147-154 contain allegations directed toward a Defendant other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

**COUNT XV – INFRINGEMENT OF THE '673 PATENT BY ORCHID**

155. Plaintiff realleges paragraphs 1-154 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-154, as if fully set forth herein.

156. Upon information and belief, Defendant Orchid submitted ANDA No. 91-113 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 91-113 seeks the FDA approval necessary to engage in the commercial manufacture, use and sale of generic tablets containing 1 mg, 2 mg or 3 mg of the active ingredient eszopiclone prior to the expiration of the '673 patent. ANDA No. 91-113 specifically seeks FDA approval to market a proposed generic version of Sepracor's Lunesta® brand 1 mg, 2 mg and 3 mg eszopiclone tablets prior to the expiration of the '673 patent.

**ANSWER:** Paragraph 156 contains legal conclusions to which no answer is required. To the extent an answer is required, Orchid admits that Orchid Healthcare (an operating division of Orchid Ltd.) submitted an Abbreviated New Drug Application ("ANDA") to the FDA seeking approval for Eszopiclone Tablets, 1 mg, 2 mg and 3 mg, before the expiration of the '673 patent. Orchid denies that Orgenus submitted such an ANDA. Orchid denies all remaining allegations of this Paragraph.

157. ANDA No. 91-113 alleges under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '673 patent are either invalid or not infringed by the manufacture, use or sale of the proposed generic versions of Sepracor's Lunesta® brand products. Sepracor received written notification of ANDA No. 91-113 and the § 505(j)(2)(A)(vii)(IV) allegations on February 20, 2009.

**ANSWER:** Paragraph 157 contains legal conclusions to which no answer is required. To the extent an answer is required, Orchid admits that Orchid Healthcare's ANDA contains a so-called "Paragraph IV Certification," stating that the '673 patent is invalid, unenforceable and/or will not be infringed by the manufacture, sale or use of the drug products for which Orchid Healthcare submitted its ANDA. Orchid further admits, on information and belief, that Sepracor received the required notice of Orchid Healthcare's ANDA on or about February 20, 2009. Orchid denies all remaining allegations of this Paragraph.

158. Orchid's submission to the FDA of ANDA No. 91-113, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '673 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

159. Orchid Healthcare, Orchid Ltd. and Orgenus are jointly and severally liable for any infringement of the '673 patent. This is because, upon information and belief, Orchid Healthcare, Orchid Ltd. and Orgenus actively and knowingly caused to be submitted, assisted with, participated in, contributed to and/or directed the submission of ANDA No. 91-113 and the § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

**ANSWER:** Denied.

160. Orchid's active and knowing participation in, contribution to, aiding, abetting and/or inducement of the submission to the FDA of ANDA No. 91-113 and the § 505(j)(2)(A)(vii)(IV) allegations constitutes infringement of the '673 patent under 35 U.S.C. § 271(e)(2)(A). Orchid's commercial manufacture, use, offer for sale, importation or sale of its proposed generic versions of Sepracor's Lunesta® brand products, or inducement of or contribution to such conduct, would further infringe the '673 patent under 35 U.S.C. § 271(a), (b) and/or (c).

**ANSWER:** Denied.

161. Upon information and belief, Orchid was aware of the existence of the '673 patent and was aware that filing of the ANDA and certification with respect to the '673 patent constituted an act of infringement of that patent.

**ANSWER:** Paragraph 161 contains legal conclusions to which no answer is required. To the extent an answer is required, Orchid admits that Orchid Healthcare was aware of the '673 patent when Orchid Healthcare submitted its ANDA. Orchid denies all remaining allegations of this Paragraph.

162. This case is an exceptional one and Sepracor is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**ANSWER:** Denied.

163. Sepracor will be irreparably harmed by Orchid's infringing activities unless those activities are enjoined by this Court. Sepracor does not have an adequate remedy at law.

**ANSWER:** Denied.

#### **COUNT XVI – INFRINGEMENT OF THE '673 PATENT BY LUPIN**

164. Plaintiff realleges paragraphs 1-163 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-163, as if fully set forth herein.

165. – 172.

**ANSWER:** Paragraphs 165-172 contain allegations directed toward a Defendant other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

#### **COUNT XVII – INFRINGEMENT OF THE '673 PATENT BY SUN**

173. Plaintiff realleges paragraphs 1-172 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-172, as if fully set forth herein.

174. – 181.

**ANSWER:** Paragraphs 174-181 contain allegations directed toward a Defendant other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

#### **COUNT XVIII – INFRINGEMENT OF THE '673 PATENT BY ALPHAPHARM**

182. Plaintiff realleges paragraphs 1-181 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-181, as if fully set forth herein.

183. – 190.

**ANSWER:** Paragraphs 183-190 contain allegations directed toward a Defendant other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

**INFRINGEMENT OF THE '926 PATENT**

**COUNT XIX – INFRINGEMENT OF THE '926 PATENT BY REDDY**

191. Plaintiff realleges paragraphs 1-190 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-190, as if fully set forth herein.

192. – 199.

**ANSWER:** Paragraphs 192-199 contain allegations directed toward a Defendant other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

**COUNT XX – INFRINGEMENT OF THE '926 PATENT BY ROXANE**

200. Plaintiff realleges paragraphs 1-199 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-199, as if fully set forth herein.

201. – 207.

**ANSWER:** Paragraphs 201-207 contain allegations directed toward a Defendant other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

**COUNT XXI – INFRINGEMENT OF THE '926 PATENT BY COBALT**

208. Plaintiff realleges paragraphs 1-207 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-207, as if fully set forth herein.

209. – 216.

**ANSWER:** Paragraphs 209-216 contain allegations directed toward a Defendant other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

**COUNT XXII – INFRINGEMENT OF THE '926 PATENT BY GLENMARK**

217. Plaintiff realleges paragraphs 1-216 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-216, as if fully set forth herein.

218. – 225.

**ANSWER:** Paragraphs 218-225 contain allegations directed toward a Defendant other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

**COUNT XXIII – INFRINGEMENT OF THE '926 PATENT BY ORCHID**

226. Plaintiff realleges paragraphs 1-225 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-225, as if fully set forth herein.

227. Upon information and belief, Defendant Orchid submitted ANDA No. 91-113 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 91-113 seeks the FDA approval necessary to engage in the commercial manufacture, use and sale of generic tablets containing 1 mg, 2 mg or 3 mg of the active ingredient eszopiclone prior to the expiration of the '926 patent. ANDA No. 91-113 specifically seeks FDA approval to market a proposed generic version of Sepracor's Lunesta® brand 1 mg, 2 mg and 3 mg eszopiclone tablets prior to the expiration of the '926 patent.

**ANSWER:** Paragraph 227 contains legal conclusions to which no answer is required. To the extent an answer is required, Orchid admits that Orchid Healthcare (an operating division of Orchid Ltd.) submitted an Abbreviated New Drug Application ("ANDA") to the FDA seeking approval for Eszopiclone Tablets, 1 mg, 2 mg and 3 mg, before the

expiration of the '926 patent. Orchid denies that Orgenus submitted such an ANDA. Orchid denies all remaining allegations of this Paragraph.

228. ANDA No. 91-113 alleges under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '926 patent are either invalid or not infringed by the manufacture, use or sale of the proposed generic versions of Sepracor's Lunesta® brand products. Sepracor received written notification of ANDA No. 91-113 and the § 505(j)(2)(A)(vii)(IV) allegations on February 20, 2009.

**ANSWER:** Paragraph 228 contains legal conclusions to which no answer is required. To the extent an answer is required, Orchid admits that Orchid Healthcare's ANDA contains a so-called "Paragraph IV Certification," stating that the '926 patent is invalid, unenforceable and/or will not be infringed, either directly or indirectly, by the manufacture, sale or use of the drug products for which Orchid Healthcare submitted its ANDA. Orchid further admits, on information and belief, that Sepracor received the required notice of Orchid Healthcare's ANDA on or about February 20, 2009. Orchid denies all remaining allegations of this Paragraph.

229. Orchid's submission to the FDA of ANDA No. 91-113, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '926 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

230. Orchid Healthcare, Orchid Ltd. and Orgenus are jointly and severally liable for any infringement of the '926 patent. This is because, upon information and belief, Orchid Healthcare, Orchid Ltd. and Orgenus actively and knowingly caused to be submitted, assisted with, participated in, contributed to and/or directed the submission of ANDA No. 91-113 and the § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

**ANSWER:** Denied.

231. Orchid's active and knowing participation in, contribution to, aiding, abetting and/or inducement of the submission to the FDA of ANDA No. 91-113 and the § 505(j)(2)(A)(vii)(IV) allegations constitutes infringement of the '926 patent under 35 U.S.C. § 271(e)(2)(A). Orchid's commercial manufacture, use, offer for sale, importation or sale of its proposed generic versions of Sepracor's Lunesta® brand products, or inducement of or contribution to such conduct, would further infringe the '926 patent under 35 U.S.C. § 271(a), (b) and/or (c).

**ANSWER:** Denied.

232. Upon information and belief, Orchid was aware of the existence of the '926 patent and was aware that filing of the ANDA and certification with respect to the '926 patent constituted an act of infringement of that patent.

**ANSWER:** Paragraph 232 contains legal conclusions to which no answer is required. To the extent an answer is required, Orchid admits that Orchid Healthcare was aware of the '926 patent when Orchid Healthcare submitted its ANDA. Orchid denies all remaining allegations of this Paragraph.

233. This case is an exceptional one and Sepracor is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**ANSWER:** Denied.

234. Sepracor will be irreparably harmed by Orchid's infringing activities unless those activities are enjoined by this Court. Sepracor does not have an adequate remedy at law.

**ANSWER:** Denied.

#### **COUNT XXIV – INFRINGEMENT OF THE '926 PATENT BY LUPIN**

235. Plaintiff realleges paragraphs 1-234 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-234, as if fully set forth herein.

236. – 243.

**ANSWER:** Paragraphs 236-243 contain allegations directed toward a Defendant other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

#### **COUNT XXV – INFRINGEMENT OF THE '926 PATENT BY SUN**

244. Plaintiff realleges paragraphs 1-243 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-243, as if fully set forth herein.

245. – 252.

**ANSWER:** Paragraphs 245-252 contain allegations directed toward a Defendant other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

**COUNT XXVI – INFRINGEMENT OF THE '926 PATENT BY SUN**

253. Plaintiff realleges paragraphs 1-252 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-252, as if fully set forth herein.

254. – 261.

**ANSWER:** Paragraphs 254-261 contain allegations directed toward a Defendant other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

**INFRINGEMENT OF THE '724 PATENT**

**COUNT XXVII – INFRINGEMENT OF THE '724 PATENT BY REDDY**

262. Plaintiff realleges paragraphs 1-261 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-261, as if fully set forth herein.

263. – 270.

**ANSWER:** Paragraphs 263-270 contain allegations directed toward a Defendant other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

**COUNT XXVIII – INFRINGEMENT OF THE '724 PATENT BY ROXANE**

271. Plaintiff realleges paragraphs 1-270 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-270, as if fully set forth herein.

272. – 277.

**ANSWER:** Paragraphs 272-277 contain allegations directed toward a Defendant other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

**COUNT XXIX – INFRINGEMENT OF THE '724 PATENT BY COBALT**

278. Plaintiff realleges paragraphs 1-277 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-277, as if fully set forth herein.

279. – 286.

**ANSWER:** Paragraphs 279-286 contain allegations directed toward a Defendant other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

**COUNT XXX – INFRINGEMENT OF THE '724 PATENT BY GLENMARK**

287. Plaintiff realleges paragraphs 1-286 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-286, as if fully set forth herein.

288. – 295.

**ANSWER:** Paragraphs 288-295 contain allegations directed toward a Defendant other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

**COUNT XXXI – INFRINGEMENT OF THE '724 PATENT BY ORCHID**

296. Plaintiff realleges paragraphs 1-295 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-295, as if fully set forth herein.

297. Upon information and belief, Defendant Orchid submitted ANDA No. 91-113 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 91-113 seeks the FDA approval necessary to engage in the commercial manufacture, use and sale of generic tablets containing 1 mg, 2 mg or 3 mg of the active ingredient eszopiclone prior to the expiration of the '724 patent. ANDA No. 91-113 specifically seeks FDA approval to market a proposed generic version of Sepracor's Lunesta® brand 1 mg, 2 mg and 3 mg eszopiclone tablets prior to the expiration of the '724 patent.

**ANSWER:** Paragraph 297 contains legal conclusions to which no answer is required. To the extent an answer is required, Orchid admits that Orchid Healthcare (an operating division of Orchid Ltd.) submitted an Abbreviated New Drug Application ("ANDA") to the FDA seeking approval for Eszopiclone Tablets, 1 mg, 2 mg and 3 mg, before the expiration of the '724 patent. Orchid denies that Organus submitted such an ANDA. Orchid denies all remaining allegations of this Paragraph.

298. ANDA No. 91-113 alleges under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '724 patent are either invalid or not infringed by the manufacture, use or sale of the proposed generic versions of Sepracor's Lunesta® brand products. Sepracor received written notification of ANDA No. 91-113 and the § 505(j)(2)(A)(vii)(IV) allegations on February 20, 2009.

**ANSWER:** Paragraph 298 contains legal conclusions to which no answer is required. To the extent an answer is required, Orchid admits that Orchid Healthcare's ANDA contains a so-called "Paragraph IV Certification," stating that the '724 patent is invalid, unenforceable and/or will not be infringed, either directly or indirectly, by the manufacture, sale or use of the drug products for which Orchid Healthcare submitted its ANDA. Orchid further admits, on information and belief, that Sepracor received the required notice of Orchid Healthcare's ANDA on or about February 20, 2009. Orchid denies all remaining allegations of this Paragraph.

299. Orchid's submission to the FDA of ANDA No. 91-113, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '724 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

300. Orchid Healthcare, Orchid Ltd. and Orgenus are jointly and severally liable for any infringement of the '724 patent. This is because, upon information and belief, Orchid Healthcare, Orchid Ltd. and Orgenus actively and knowingly caused to be submitted, assisted with, participated in, contributed to and/or directed the submission of ANDA No. 91-113 and the § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

**ANSWER:** Denied.

301. Orchid's active and knowing participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 91-113 and the § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '724 patent under 35 U.S.C. § 271(e)(2)(A). Orchid's commercial use, offer for sale, importation or sale of its proposed generic versions of Sepracor's Lunesta® brand products, or inducement of or contribution to such conduct, would further infringe the '724 patent under 35 U.S.C. § 271(a), (b) and/or (c).

**ANSWER:** Denied.

302. Upon information and belief, Orchid was aware of the existence of the '724 patent and was aware that filing of the ANDA and certification with respect to the '724 patent constituted an act of infringement of that patent.

**ANSWER:** Paragraph 302 contains legal conclusions to which no answer is required. To the extent an answer is required, Orchid admits that Orchid Healthcare was aware of the '724 patent when Orchid Healthcare submitted its ANDA. Orchid denies all remaining allegations of this Paragraph.

303. This case is an exceptional one and Sepracor is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

**ANSWER:** Denied.

304. Sepracor will be irreparably harmed by Orchid's infringing activities unless those activities are enjoined by this Court. Sepracor does not have an adequate remedy at law.

**ANSWER:** Denied.

#### **COUNT XXXII – INFRINGEMENT OF THE '724 PATENT BY LUPIN**

305. Plaintiff realleges paragraphs 1-304 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-304, as if fully set forth herein.

306. – 313.

**ANSWER:** Paragraphs 306-313 contain allegations directed toward a Defendant other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

**COUNT XXXIII – INFRINGEMENT OF THE '724 PATENT BY SUN**

314. Plaintiff realleges paragraphs 1-313 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-313, as if fully set forth herein.

315. – 322.

**ANSWER:** Paragraphs 315-322 contain allegations directed toward a Defendant other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

**COUNT XXXIV – INFRINGEMENT OF THE '724 PATENT BY ALPHAPHARM**

323. Plaintiff realleges paragraphs 1-322 as if fully set forth herein.

**ANSWER:** Orchid repeats, re-asserts and incorporates by reference its responses to Paragraphs 1-322, as if fully set forth herein.

324. – 331.

**ANSWER:** Paragraphs 324-331 contain allegations directed toward a Defendant other than Orchid, and therefore no answer by Orchid is required. To the extent an answer by Orchid is required, Orchid denies the allegations of these Paragraphs.

\* \* \*

Orchid denies all remaining allegations not specifically admitted herein. Orchid further denies that Sepracor is entitled to the relief requested, or to any relief whatsoever. Orchid respectfully requests that the Court: (a) dismiss the Complaint with prejudice; (b) enter judgment in favor of Orchid; (c) award Orchid the reasonable attorneys' fees and costs of defending this action pursuant to 35 U.S.C. § 285; and (d) award Orchid such further relief as the Court deems just and appropriate.

**DEFENSES**

Without undertaking any of the burdens imposed by law on Sepracor, and without admitting any of the allegations in the Complaint not otherwise admitted, Orchid asserts the following defenses:

**First Defense**

The claims of U.S. Patent No. 6,319,926 ("the '926 patent") are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

**Second Defense**

The manufacture, use, sale, offer for sale, or importation of the eszopiclone products that are the subject of Orchid Healthcare's ANDA have not infringed, do not infringe, and would not, if made, imported, or marketed, infringe any valid and/or enforceable claim of the '926 patent.

**Third Defense**

Orchid has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and/or enforceable claim of the '926 patent.

**Fourth Defense**

The claims of U.S. Patent No. 6,444,673 (“the ‘673 patent”) are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code and/or for obviousness-type double patenting.

**Fifth Defense**

The manufacture, use, sale, offer for sale, or importation of the eszopiclone products that are the subject of Orchid Healthcare’s ANDA have not infringed, do not infringe, and would not, if made, imported, or marketed, infringe any valid and/or enforceable claim of the ‘673 patent.

**Sixth Defense**

The claims of U.S. Patent No. 6,864,257 (“the ‘257 patent”) are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code and/or for obviousness-type double patenting.

**Seventh Defense**

The manufacture, use, sale, offer for sale, or importation of the eszopiclone products that are the subject of Orchid Healthcare’s ANDA have not infringed, do not infringe, and would not, if made, imported, or marketed, infringe any valid and/or enforceable claim of the ‘257 patent.

**Eighth Defense**

Orchid has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and/or enforceable claim of the ‘257 patent.

**Ninth Defense**

The claims of U.S. Patent No. 7,381,724 ("the '724 patent") are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

**Tenth Defense**

The manufacture, use, sale, offer for sale, or importation of the eszopiclone products that are the subject of Orchid Healthcare's ANDA have not infringed, do not infringe, and would not, if made, imported, or marketed, infringe any valid and/or enforceable claim of the '724 patent.

**Eleventh Defense**

Orchid has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and/or enforceable claim of the '724 patent.

**Twelfth Defense**

The Complaint fails to state a claim upon which relief can be granted.

**Thirteenth Defense**

Orgenus is not a proper party to this suit.

**Fourteenth Defense**

The Court lacks subject matter jurisdiction over any claims directed against Orgenus.

**Fifteenth Defense**

Any additional defenses or counterclaims that discovery may reveal.

**COUNTERCLAIMS**

To the extent that the Court has subject matter jurisdiction over Sepracor's claims, Defendants/Counterclaim-Plaintiffs Orchid Healthcare, Orchid Chemicals & Pharmaceuticals, Ltd. ("Orchid Ltd.") and Orgenus Pharma Inc. ("Orgenus") (collectively, "Orchid"), by way of Counterclaims against Plaintiff/Counterclaim-Defendant Sepracor Inc. ("Sepracor"), allege as follows:

**THE PARTIES**

1. Orchid Healthcare is an operating division of Orchid Chemicals & Pharmaceuticals Ltd. ("Orchid Ltd."), having a place of business at Plot Nos. B3 – B6 & B11 – B14, SIPCOT Industrial Park, Irungattukottai—602 105, Sriperumbudur, Kancheepuram District, India.

2. Orchid Chemicals & Pharmaceuticals, Ltd. ("Orchid Ltd.") is an Indian corporation having a place of business at Orchid Towers, #313, Valluvar Kottam High Road, Nungambakkam, Chennai – 600 034, Tamil Nadu, India.

3. Orgenus Pharma Inc. ("Orgenus") is a company organized and existing under the laws of the State of New Jersey with a place of at 700 Alexander Park, Suite 104, Princeton, New Jersey 08540.

4. On information and belief, Sepracor Inc. ("Sepracor") purports and claims to be a company organized and existing under the laws of the State of Delaware with its principal place of business at 84 Waterford Drive, Marlborough, MA 01752.

**JURISDICTION AND VENUE**

5. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. To the extent that the Court has subject matter jurisdiction over Sepracor's claims, this Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Sepracor because Sepracor has availed itself of the rights and privileges of this forum by suing Orchid in this District, and because Sepracor conducts substantial business in, and has regular and systematic contact with, this District.

8. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c) and 1400(b).

**Patents-in-Suit**

9. On or about November 20, 2001, the U.S. Patent and Trademark Office issued U.S. Patent No. 6,319,926 ("the '926 patent"), entitled "Optically Active 5H-pyrrolo[3,4-b]pyrazine Derivative, Its Preparation And Pharmaceutical Compositions Containing It," to Claude Cotrel and Gérard Roussel.

10. On or about September 3, 2002, the U.S. Patent and Trademark Office issued U.S. Patent No. 6,444,673 ("the '673 patent"), entitled "Optically Active 5H-pyrrolo[3,4-b]pyrazine Derivative, Its Preparation And Pharmaceutical Compositions Containing It," to Claude Cotrel and Gérard Roussel.

11. On or about March 8, 2005, the U.S. Patent and Trademark Office issued U.S. Patent No. 6,864,257 ("the '257 patent"), entitled "Optically Active 5H-pyrrolo[3,4-b]pyrazine Derivative, Its Preparation And Pharmaceutical Compositions Containing It," to Claude Cotrel and Gérard Roussel.

12. On or about June 3, 2008, the U.S. Patent and Trademark Office issued U.S. Patent No. 7,381,724 ("the '724 patent"), entitled "Optically Active 5H-pyrrolo[3,4-b]pyrazine

Derivative, Its Preparation And Pharmaceutical Compositions Containing Same," to Claude Cotrel and Gérard Roussel.

13. Sepracor purports and claims to own, and to have the right to enforce, the '926, '673, '257 and '724 patents.

14. On or about March 20, 2009, Sepracor sued Orchid in this District alleging infringement of the '926, '673, '257 and '724 patents under 35 U.S.C. § 271(e)(2)(A).

**COUNT I**  
**(Declaratory Judgment of Non-Infringement of the '926 Patent)**

15. Orchid adopts by reference, repeats, and realleges its specific responses and averments in paragraphs 1-14 above as if fully set forth herein.

16. To the extent that the Court has subject matter jurisdiction over Sepracor's claims, there is an actual, substantial, and continuing justiciable case or controversy between Orchid and Sepracor regarding non-infringement of the '926 patent.

17. The manufacture, use, sale, offer for sale, or importation of the eszopiclone products that are the subject of Orchid Healthcare's ANDA have not infringed, do not infringe, and would not, if made, imported or marketed, infringe any valid and/or enforceable claim of the '926 patent, either directly or indirectly.

18. Orchid is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the eszopiclone products that are the subject of Orchid Healthcare's ANDA have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '926 patent, either directly or indirectly.

**COUNT II**  
**(Declaratory Judgment of Invalidity of the '926 Patent)**

19. Orchid adopts by reference, repeats, and realleges its specific responses and averments in paragraphs 1-18 above as if fully set forth herein.

20. To the extent that the Court has subject matter jurisdiction over Sepracor's claims, a present, genuine, and justiciable controversy exists between Orchid and Sepracor regarding, *inter alia*, the invalidity of the '926 patent.

21. The claims of the '926 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

22. Orchid is entitled to a judicial declaration that the claims of the '926 patent are invalid.

**COUNT III**  
**(Declaratory Judgment of Non-Infringement of the '673 Patent)**

23. Orchid adopts by reference, repeats, and realleges its specific responses and averments in paragraphs 1-22 above as if fully set forth herein.

24. To the extent that the Court has subject matter jurisdiction over Sepracor's claims, there is an actual, substantial, and continuing justiciable case or controversy between Orchid and Sepracor regarding non-infringement of the '673 patent.

25. The manufacture, use, sale, offer for sale, or importation of the eszopiclone products that are the subject of Orchid Healthcare's ANDA have not infringed, do not infringe, and would not, if made, imported or marketed, infringe any valid and/or enforceable claim of the '673 patent.

26. Orchid is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the eszopiclone products that are the subject of Orchid Healthcare's ANDA have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '673 patent.

**COUNT IV**  
**(Declaratory Judgment of Invalidity of the '673 Patent)**

27. Orchid adopts by reference, repeats, and realleges its specific responses and averments in paragraphs 1-26 above as if fully set forth herein.
28. To the extent that the Court has subject matter jurisdiction over Sepracor's claims, a present, genuine, and justiciable controversy exists between Orchid and Sepracor regarding, *inter alia*, the invalidity of the '673 patent.
29. The claims of the '673 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.
30. The claims of the '673 patent are invalid for obviousness-type double patenting.
31. Orchid is entitled to a judicial declaration that the claims of the '673 patent are invalid.

**COUNT V**  
**(Declaratory Judgment of Non-Infringement of the '257 Patent)**

32. Orchid adopts by reference, repeats, and realleges its specific responses and averments in paragraphs 1-31 above as if fully set forth herein.
33. To the extent that the Court has subject matter jurisdiction over Sepracor's claims, there is an actual, substantial, and continuing justiciable case or controversy between Orchid and Sepracor regarding non-infringement of the '257 patent.
34. The manufacture, use, sale, offer for sale, or importation of the eszopiclone products that are the subject of Orchid Healthcare's ANDA have not infringed, do not infringe, and would not, if made, imported or marketed, infringe any valid and/or enforceable claim of the '257 patent, either directly or indirectly.

35. Orchid is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the eszopiclone products that are the subject of Orchid Healthcare's ANDA have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '257 patent, either directly or indirectly.

**COUNT VI**  
**(Declaratory Judgment of Invalidity of the '257 Patent)**

36. Orchid adopts by reference, repeats, and realleges its specific responses and averments in paragraphs 1-35 above as if fully set forth herein.

37. To the extent that the Court has subject matter jurisdiction over Sepracor's claims, a present, genuine, and justiciable controversy exists between Orchid and Sepracor regarding, *inter alia*, the invalidity of the '257 patent.

38. The claims of the '257 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

39. The claims of the '257 patent are invalid for obviousness-type double patenting.

40. Orchid is entitled to a judicial declaration that the claims of the '257 patent are invalid.

**COUNT VII**  
**(Declaratory Judgment of Non-Infringement of the '724 Patent)**

41. Orchid adopts by reference, repeats, and realleges its specific responses and averments in paragraphs 1-40 above as if fully set forth herein.

42. To the extent that the Court has subject matter jurisdiction over Sepracor's claims, there is an actual, substantial, and continuing justiciable case or controversy between Orchid and Sepracor regarding non-infringement of the '724 patent.

43. The manufacture, use, sale, offer for sale, or importation of the eszopiclone products that are the subject of Orchid Healthcare's ANDA have not infringed, do not infringe,

and would not, if made, imported or marketed, infringe any valid and/or enforceable claim of the ‘724 patent, either directly or indirectly.

44. Orchid is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the eszopiclone products that are the subject of Orchid Healthcare’s ANDA have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ‘724 patent, either directly or indirectly.

**COUNT VIII**  
**(Declaratory Judgment of Invalidity of the ‘724 Patent)**

45. Orchid adopts by reference, repeats, and realleges its specific responses and averments in paragraphs 1-44 above as if fully set forth herein.

46. To the extent that the Court has subject matter jurisdiction over Sepracor’s claims, a present, genuine, and justiciable controversy exists between Orchid and Sepracor regarding, *inter alia*, the invalidity of the ‘724 patent.

47. The claims of the ‘724 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

48. Orchid is entitled to a judicial declaration that the claims of the ‘724 patent are invalid.

WHEREFORE, Orchid Healthcare, Orchid Chemicals & Pharmaceuticals Ltd. and Organon Pharma Inc. respectfully pray for judgment in their favor and against Sepracor Inc.:

- a. Declaring that the manufacture, use, sale, offer for sale, or importation of the eszopiclone products that are the subject of Orchid Healthcare’s ANDA have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ‘926 patent, either directly or indirectly;
- b. Declaring that the claims of the ‘926 patent are invalid;

- c. Declaring that the manufacture, use, sale, offer for sale, or importation of the eszopiclone products that are the subject of Orchid Healthcare's ANDA have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '673 patent, either directly or indirectly;
- d. Declaring that the claims of the '673 patent are invalid;
- e. Declaring that the manufacture, use, sale, offer for sale, or importation of the eszopiclone products that are the subject of Orchid Healthcare's ANDA have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '257 patent, either directly or indirectly;
- f. Declaring that the claims of the '257 patent are invalid;
- g. Declaring that the manufacture, use, sale, offer for sale, or importation of the eszopiclone products that are the subject of Orchid Healthcare's ANDA have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '724 patent, either directly or indirectly;
- h. Declaring that the claims of the '724 patent are invalid;
- i. Ordering that Plaintiff/Counterclaim-Defendant's complaint be dismissed with prejudice and judgment entered in favor of Orchid;
- j. Declaring this case exceptional and awarding Orchid its reasonable attorneys' fees and costs under 35 U.S.C. § 285; and
- k. Awarding Orchid such other and further relief as the Court may deem just and proper.

**JURY DEMAND**

Defendants/Counterclaim-Plaintiffs hereby demand a trial by jury as to all issues so triable.

Respectfully submitted,

CARELLA, BYRNE, BAIN, GILFILLAN,  
CECCHI, STEWART & OLSTEIN

Dated: May 20, 2009

/s/ James E. Cecchi

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**CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2 & 40.1**

On behalf of Defendants Orchid Healthcare, Orchid Chemicals & Pharmaceuticals Ltd. and Orgenus Pharma Inc., I hereby certify that, to the best of my knowledge, and on information and belief, the matter in controversy is not the subject of any other action, arbitration or administrative proceeding.

CARELLA, BYRNE, BAIN, GILFILLAN,  
CECCHI, STEWART & OLSTEIN

Dated: May 20, 2009

/s/ James E. Cecchi

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**CERTIFICATE OF SERVICE**

I, James E. Cecchi, hereby certify that I caused a true and correct copy of the foregoing ANSWER, DEFENSES AND COUNTERCLAIMS to be served via the Court's electronic filing system (ECF) and FedEx® overnight delivery upon:

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